

FILED IN OPEN COURT

DATE: 7/6/05TIME: 1:45 pmINITIALS: JE

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
WESTERN DIVISION

UNITED STATES OF AMERICA,

PLAINTIFF,

vs.

CR. NO. 03-20433-B

GEORGE KINDNESS

AND

AMSCOT MEDICAL LABS, INC.,

DEFENDANTS.

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PLEA AGREEMENT

The United States of America ("United States") and George Kindness ("Kindness") and Amscot Medical Labs, Inc., ("Amscot") the defendants in this action, hereby agree to the following terms, conditions and understandings:

1. Defendant Kindness agrees to enter a plea of guilty to Count 11 of the indictment, to wit, being aided and abetted in the introduction of a misbranded drug into interstate commerce with the intent to mislead, the drug being misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that its labeling did not bear adequate directions for use, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The United States and defendant Kindness stipulate and agree that the factual basis for the guilty plea in this instance is contained in the Stipulation of Facts, which has been signed by both parties and is specifically incorporated herein as Exhibit A.

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2. Defendant Amscot agrees to enter a plea of guilty to Count 11 of the indictment, to wit, being aided and abetted in the introduction of a misbranded drug into interstate commerce with the intent to mislead, the drug being misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that its labeling did not bear adequate directions for use, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The United States and defendant Amscot stipulate and agree that the factual basis for the guilty plea in this instance is contained in the Stipulation of Facts, which has been signed by both parties and is specifically incorporated herein as Exhibit A.

3. As to defendant Kindness, the parties agree that the maximum penalty for a violation of 21 U.S.C. §§ 331(a) and 333(a)(2) is imprisonment for no more than three (3) years, see 21 U.S.C. § 333(a)(2), a fine of no more than \$250,000.00, see 18 U.S.C. § 3571(b)(4), a period of supervised release of no more than one (1) year, see 18 U.S.C. § 3583(b)(3), and a mandatory special assessment of \$100.00, see 18 U.S.C. § 3013(a)(2)(A).

4. As to defendant Amscot, the parties agree that the maximum penalty for a violation of 21 U.S.C. §§ 331(a) and 333(a)(2) is imprisonment for no more than three (3) years, see 21 U.S.C. § 333(a)(2), a fine of no more than \$500,000.00, see 18 U.S.C. § 3571(c)(3), a period of supervised release of no more than one (1) year, see 18 U.S.C. § 3583(b)(3), and a mandatory special assessment of \$400.00, see 18 U.S.C. § 3013(a)(2)(B).

5. As to defendants Kindness and Amscot, the United States agrees that it will recommend the dismissal of counts 1 through 10 and 12 through 21 of the indictment, pursuant to Fed. R. Crim. P. 11(c)(1)(A), following sentencing in this case.

6. Pursuant to Fed. R. Crim. P. 11(c)(1)(B), the United States agrees that it will recommend that defendant Kindness be sentenced to the low end of the applicable guideline sentencing range. The United States and Kindness further agree that this provision of the plea agreement shall not be binding upon the district court.

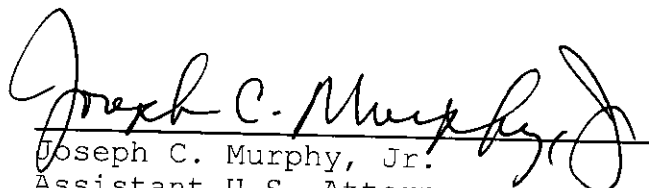
7. The United States agrees that if the defendants admit their guilt and comply with the provisions of United States Sentencing Guidelines § 3E1.1, it will not oppose the defendants receiving an appropriate reduction for acceptance of responsibility pursuant to United States Sentencing Guidelines § 3E1.1.

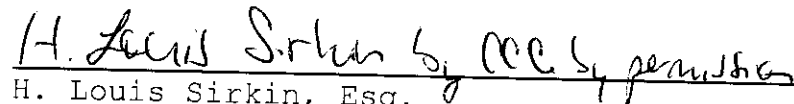
8. The parties hereto agree that the conduct described in Paragraph 8 of the Stipulation of Facts, which is attached hereto as Exhibit A, and which is attributable to defendant Kindness, does not constitute obstruction of justice as defined by United States Sentencing Guidelines § 3C1.1 in that the described conduct did not obstruct or impede the administration of justice during the course of the investigation and prosecution of this case.


9. The parties hereto agree that this agreement constitutes the parties' entire agreement and that this agreement may only be


amended in a writing signed by all the parties hereto.

The undersigned parties do hereby consent and agree to the terms herein this 6th day of July, 2005.

  
\_\_\_\_\_  
Joseph C. Murphy, Jr.  
Assistant U.S. Attorney

  
\_\_\_\_\_  
H. Louis Sirkin, Esq.  
Attorney for Defendants  
George Kindness and Amscot Medical Labs, Inc.

  
\_\_\_\_\_  
Candace C. Crouse, Esq.  
Attorney for Defendants  
George Kindness and Amscot Medical Labs, Inc.

  
\_\_\_\_\_  
George Kindness  
Defendant

  
\_\_\_\_\_  
Authorized Agent of Amscot Medical Labs, Inc.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
WESTERN DIVISION

UNITED STATES OF AMERICA,

PLAINTIFF,

vs.

CR. NO. 03-20433-B

GEORGE KINDNESS

AND

AMSCOT MEDICAL LABS, INC.,

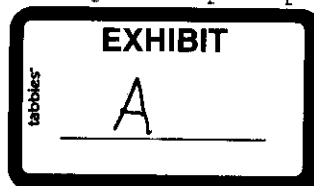
DEFENDANTS.

STIPULATION OF FACTS

The United States of America ("United States") and George Kindness ("Kindness") and Amscot Medical Labs, Inc., ("Amscot") the defendants in this action, hereby stipulate to the following facts:

1. Defendant Kindness is currently the president and part-owner of defendant Amscot Medical Labs, Inc., and has held the position of president of the corporation and been part-owner of the corporation since January, 1992. Kindness has been the lab director for Amscot and has been active in the day-to-day operation of the business since January, 1992.

2. Amscot is an Ohio corporation engaged in the business of performing laboratory medical tests of various types and kinds. It has also engaged in the business of producing certain "vaccines" as further described herein. Amscot is incorporated in the State of Ohio and its principal place of business has been



located in the Cincinnati, Ohio area at all times relevant to this case.

3. On April 12 and 13, 1999, the Food and Drug ("FDA") Administration conducted a regulatory inspection of defendant Amscot's lab facility, which was then located at 11365 Williamson Road, Cincinnati, Ohio. During the inspection FDA inspectors discovered that Amscot was producing autologous vaccines from blood and tumor samples provided to Amscot by a medical doctor practicing in Memphis, Tennessee. The vaccine was intended to treat cancer, and the blood and tumor samples were processed by Amscot into a vaccine which was specific as to each patient. Once the production process was complete, the vaccine was shipped from Cincinnati, Ohio, to Memphis, Tennessee, via interstate common carrier. Upon arrival in Memphis, the vaccine was delivered to a medical doctor and administered to patients.

4. The vaccine described in Paragraph 3, above, was part of a study known as the Gene Activated Therapy study or "GAT." During the FDA inspection of the Amscot facility in Cincinnati, Ohio, FDA inspectors informed defendants Kindness and Amscot that FDA rules and regulations required that an Investigatory New Drug Application had to be filed with the FDA in order for the GAT study to continue. Defendant Kindness was also advised by the FDA inspectors that conducting the GAT study without an IND was in effect a violation of the Food, Drug and Cosmetic Act.

5. On or about April 15, 1999, defendant Amscot submitted an IND application to the FDA for the GAT study. The IND listed defendant Amscot as a sponsor and vaccine producer for the study. The IND was never approved by the FDA and the FDA placed a clinical hold on the GAT study. A clinical hold requires that all clinical work requested under the IND is either delayed or suspended until the IND is approved.

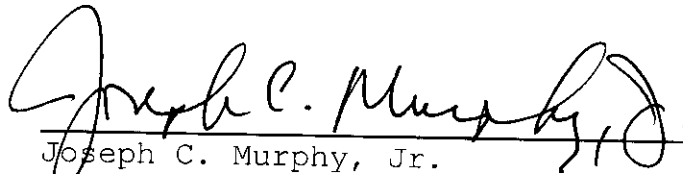
6. On December 7, 1999, through December 9, 1999, the FDA inspected the medical office of the medical doctor in Memphis, Tennessee, who had been receiving the GAT vaccines and administering them to his patients. During the inspection the FDA inspectors discovered that the medical doctor in Memphis, Tennessee, had treated some patients with Theracine, a vaccine produced by Amscot and which was almost identical to the GAT vaccine. The Theracine vaccine, just like the GAT vaccine, was manufactured from blood and tumor samples from a patient, and then injected into the patient. The FDA had never received or approved an IND for the Theracine vaccine. Kindness, through the employees of Amscot, directed the development and production of the Theracine vaccine at the Amscot lab.

7. Title 21, United States Code, § 352(f)(1) provides that a drug is "misbranded" if it fails to bear adequate directions for its use. Title 21, Code of Federal Regulations, Part 201 requires, among other things, that the label on each bottle or vial containing an investigatory new drug include information identifying the drug, directions for use and the dosage.

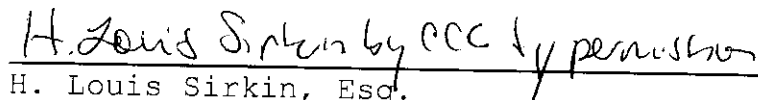
8. On or about August 3, 2000, defendants Kindness and Amscot caused a container containing Theracine to be shipped from Cincinnati, Ohio, to Memphis, Tennessee, via United Parcel Service. The shipment was delivered to a United Parcel Service facility by an Amscot employee and the employee paid for the shipping out of employee's personal funds. Once the FDA had discovered that Amscot was continuing to produce a second autologous vaccine for which an IND had not been filed, Amscot began shipment of the vaccines outside the normal course of their business. Prior to the FDA's discovery of the shipment of the new vaccine, Amscot had shipped the vaccine directly from their offices using a company account. The Theracine vaccine had been produced by Amscot from blood and tumor samples provided by the medical doctor in Memphis, Tennessee, and was intended to be used to treat cancer. The label on the container of the Theracine vaccine did not include the identity of the drug, directions for use or the dosage.



The undersigned parties do hereby stipulate to the facts set forth herein this 6th day of July, 2005.



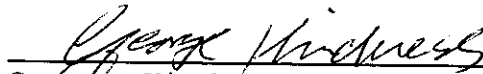
Joseph C. Murphy, Jr.  
Assistant U.S. Attorney



H. Louis Sirkin, Esq.  
Attorney for Defendants  
George Kindness and Amcscot Medical Labs, Inc.



Candace C. Crouse, Esq.  
Attorney for Defendants  
George Kindness and Amcscot Medical Labs, Inc.



George Kindness  
Defendant



Authorized Agent of Amcscot Medical Labs, Inc.

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UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
WESTERN DIVISION

UNITED STATES OF AMERICA, :  
 : Case No. CR03-20433BV  
Plaintiff, :  
 :  
v. :  
 :  
GEORGE KINDNESS and AMSCOT :  
MEDICAL LABS, INC. :  
 :  
Defendants.

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**WAIVER OF CONFLICT OF INTEREST  
OF AMSCOT MEDICAL LABS, INC.**

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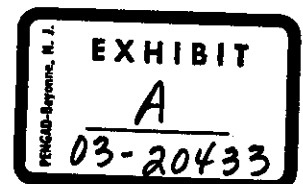
The undersigned, the President and the secretary of Amscot Medical Labs, Inc. ("Amscot"), hereby advise the Court that Amscot has been informed that it has the right to be represented by counsel independent of any obligations owed by the law firm of Sirkin, Pinales & Schwartz, LLP to Defendant, George Kindness, and while Amscot does not believe that a conflict of interest exists, Amscot hereby specifically waives its right to be represented by separate counsel in these proceedings.

George Kindness  
GEORGE KINDNESS,  
President of Amscot Medical Labs, Inc.

Date: 5<sup>th</sup> July 2005  
Sandra Kindness  
SANDRA KINDNESS,  
Secretary/Treasurer of Amscot Medical Labs, Inc.

Date: 7/5/05

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UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
WESTERN DIVISION

UNITED STATES OF AMERICA,	:	
	:	Case No. CR03-20433BV
Plaintiff,	:	
	:	
v.	:	
	:	
GEORGE KINDNESS and AMSCOT	:	
MEDICAL LABS, INC.	:	
	:	
Defendants.	:	

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WAIVER OF CONFLICT OF INTEREST  
OF GEORGE KINDNESS

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I, George Kindness, Defendant in the above-captioned criminal action, hereby advise the Court that I have been informed that I have the right to be represented by counsel independent of any obligations owed by the law firm of Sirkin, Pinales & Schwartz, LLP to Defendant, Amscot Medical Labs, Inc., and while I do not believe that a conflict of interest exists, I hereby specifically waive my right to be represented by separate counsel in these proceedings.

  
\_\_\_\_\_  
GEORGE KINDNESS

Date: 5<sup>th</sup> July 2005.

**RESOLUTION AND DECLARATION  
OF  
AMSCOT MEDICAL LABS, INC.**

The undersigned, the President and the Secretary/Treasurer of Amscot Medical Labs, Inc. (the "Company"), in accordance with the laws of the State of Ohio, hereby take the following actions and adopt the following recitals and resolutions, effective as of the date hereof.

**DECLARATION OF GOOD STANDING**

WHEREAS, the Company is in good standing in the State of Ohio and shall take all steps necessary to maintain good standing in the State of Ohio.

**WRITTEN CONSENT AND RESOLUTION**

WHEREAS, the Company desires to plead guilty to Count 11 of the Indictment in the matter entitled *United States of America v. George Kindness and Amscot Medical Labs, Inc.*, Case No. 03-20433-B.

FURTHER, the Company authorizes George Kindness to execute any documents necessary to enter into the plea of guilty as stated above.

NOW, THEREFORE, BE IT RESOLVED, the Company shall consent to the plea of guilty to Count 11 of the Indictment in the matter entitled *United States of America v. George Kindness and Amscot Medical Labs, Inc.*, Case No. 03-20433-B, and authorizes George Kindness to represent the Company and to execute any documents necessary to enter into the plea of guilty as stated above.

Dated: 5<sup>th</sup> July, 2005

Dated: 7/5/05

George Kindness  
George Kindness, President  
Sandra Kindness  
Sandra Kindness, Secretary/Treasurer



# Notice of Distribution

This notice confirms a copy of the document docketed as number 64 in case 2:03-CR-20433 was distributed by fax, mail, or direct printing on July 7, 2005 to the parties listed.

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US Marshals  
Memphis, TN

US Pretrial Office  
Memphis, TN

US Probation Office  
Memphis, TN

Honorable J. Breen  
US DISTRICT COURT